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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,699	02/08/2002	Jingrong Cao	VPI/01-103 US	2092

7590 11/25/2003

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Cambridge, MA 02139-4242

EXAMINER
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RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/25/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/071,699

Applicant(s)  
Cao et al.

Examiner  
Deepak Rao

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 22, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-42, 48-51, 54-60, 63, 65, and 67-70 ☒ are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-42, 54-60, 63, and 67-70 ☒ are allowed.
- 6) ☒ Claim(s) 48-51 and 65 ☒ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

This office action is in response to the amendment filed on September 22, 2003.

Claims 1-42, 48-51, 54-60, 63, 65 and 67-70 are present in this application.

***The following rejections are withdrawn:***

1. The rejection under 35 U.S.C. 112, second paragraph of the previous office action is hereby withdrawn in view of the amendments.
2. The obviousness-type double patenting rejection of the previous office action is hereby withdrawn in view of applicant's amendments and remarks. Applicant amended the claims to remove "comprising" from the definition of the term "Sp". Further, the reference compounds require three non-hydrogen substituents including a ring substituent ( $R^3$ ) directly attached to the thienyl ring. The instantly claimed compounds on the other hand have  $-Q'R^2$  and  $R^6$  as the only two substituent on the 5-membered ring (Sp) and neither of the substituents is a ring substituent which is directly attached to Sp. Accordingly, there is no overlap between the instant claims and the reference claims.

***The following rejections are maintained:***

Claims 48, 49 and 65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of specific types of cancer (e.g., colon cancer), does not reasonably provide enablement for the treatment of most of the other diseases

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encompassed by the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant first indicates that claim 48 is canceled, however, the claim continues to be pending and is drawn to 'treatment of cancer' generally. Also, claim 49 recites extensive list of cancers and applicant submits that all these are enabled by the specification. Applicant relies on the information provided in the background section of the specification, however, that section provides only provides 'colon, breast and other solid tumors' (see page 3, lines 3-5). However, most of the state of the art references provide the role of the kinase inhibitors in the treatment of a specific disease, see e.g., Frey which provides the role of ERK2 in breast cancer. The literature does not establish the link for many of the other types of cancers recited in the claims. See for example, <http://www.rzpd.de/ngfn/lectures/Schaefer01.html> wherein it is clearly stated that "the contribution of individual kinases is poorly understood". Also, see a recent publication <http://atlas.physbio.mssm.edu/~amjad/publications/pdf/2003/02.pdf> wherein it is clearly stated that "the structural basis of substrate recognition and the mechanism of substrate-induced catalytic activation of MKP's remain unanswered". The instant claim involves treatment of all types of cancers having diverse pathways and/or associated with different organs and the use of a single agent to provide treatment for all such diseases is contrary to what is known in the medicine.

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Claim 49 lists a variety of cancers related to solid tumors as well as blood cell proliferation. Claim 65 also recites 'treatment of cancer' in general along with many other diverse diseases such as Alzheimer's disease, HIV, etc. Applicants' reliance on the *Brana* decision is erroneous since the facts were different in more than one respect from the instant case. Compounds on appeal were of a much narrower scope and there were no method claims. Said compounds were similar in structure to compounds displaying *in vivo* anti-tumor activity based on art-recognized *in vivo* tests and also tested favorably in an *in vivo* test. Thus contrary to *Brana* it is not evident that at the time of applicants' effective filing that the instant compounds having such a diversity of substituents and a diverse "core" could be used for treating any and all of the cancer diseases recited in the instant claims.

***The following rejections are necessitated by the amendment:***

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims depend from claim 47 which has been canceled.

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***Allowable Subject Matter***

Claims 1-42, 54-60, 63 and 67-70 are allowed. The references of record do not teach or fairly suggest the instantly claimed compounds.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

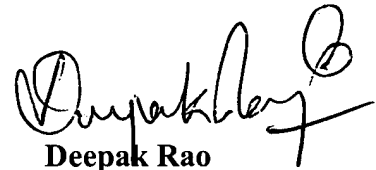
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

November 20, 2003